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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/327,750      | 06/07/1999  | TAKA-AKI SATO        | 59131/JPW/AK        | 5864             |

7590 09/08/2004

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EXAMINER

LANDSMAN, ROBERT S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |  |                     |  |
|------------------------------|------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> |  | <b>Applicant(s)</b> |  |
|                              | 09/327,750             |  | SATO, TAKA-AKI      |  |
|                              | <b>Examiner</b>        |  | <b>Art Unit</b>     |  |
|                              | Robert Landsman        |  | 1647                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 134-136, 139-143 and 146 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 134-136, 139-143, 146 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Amendment dated 8/19/04 has been entered into the record.
- B. Claims 134-146 were pending in the application. In the Amendment dated 8/19/04 Applicants canceled claims 137, 138, 144 and 145. Therefore, claims 134-136, 139-143 and 146 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Claim Rejections - 35 USC § 112, second paragraph – scope of enablement***

- A. The rejection of claims 134-136, 139-143 and 146 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments. The specification does recite numerous NADE sequences, SEQ ID NO:12, 13 and 30-39. Though Applicants have only provided a working example of SEQ ID NO:12, the Examiner, in light of the knowledge in the art as to the structural and functional domains of NADE proteins (such as residues 338-393, NES and ubiquitination domains), as argued by Applicants, cannot make a prima facie case demonstrating that SEQ ID NO:13 and 30-39 are not NADE proteins. Therefore, Applicants have provided sufficient guidance and examples of NADE proteins.

### ***3. Claim Rejections - 35 USC § 112, second paragraph – written description***

- A. The rejection of claims 134-136, 139-143 and 146 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments. The specification does recite numerous NADE sequences, SEQ ID NO:12, 13 and 30-39. Though Applicants have only provided demonstrated the function of SEQ ID NO:12, the Examiner, in light of the knowledge in the art as to the structural and functional domains of NADE proteins (such as residues 338-393, NES and ubiquitination domains), as argued by Applicants, cannot make a prima facie case demonstrating that SEQ ID NO:13 and 30-39 are not NADE proteins. Therefore, Applicants have provided adequate written description of NADE proteins.

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**4. Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 134-136, 139-143 and 146 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The invention is the association of NADE and p75 and its relationship to apoptosis. However, claims 139-143 and 146 do not require any measurement of a NADE/p75 interaction, nor is there any control to demonstrate that the test agent is affecting the NADE/p75 interaction. All that the claims are determining is the expression level of NADE. In the claims requiring an intact cell, the agent could be affecting apoptosis by other mechanisms other than a NADE/p75 pathway and it is not clear that an agent which simply affects NADE expression will cause apoptosis in that cell. None of the pending claims recite a method step which requires a measurement of apoptosis. Therefore, the claims should recite something to the effect of, for example, "a method for determining whether an agent has the potential to decrease/increase apoptosis..." unless Applicants amend the claims to recite a step which determines the agent's effect on actual apoptosis.

**5. Conclusion**

A. No claim is allowable.

**Advisory information**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
September 01, 2004

  
**ROBERT LANDSMAN**  
**PATENT EXAMINER**